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A study to evaluate the safety and processing of RO7434656 by the body and the effects it has in healthy Chinese participants

Submission date 20/08/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/08/2024	**Overall study status** Completed	
Last Edited 14/04/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Immunoglobulin A nephropathy (IgAN) is a disease in which IgA, a protein produced by the immune system, builds up and damages the filtering part of the kidney causing chronic kidney disease and kidney failure. This study is testing a medicine called RO7434656. It is being developed to treat IgAN. RO7434656 is an experimental medicine. This means health authorities (like the US Food and Drug Administration and European Medicines Agency) have not approved RO7434656 for the treatment of IgAN. This study aims to test the safety of RO7434656 (at different doses) and to understand what happens to RO7434656 once it is in the body.

Who can participate?
Healthy Chinese people aged 18-65 years. Participants may not be able to take part in this study if they have a history or presence of any significant diseases. People who are pregnant, or currently breastfeeding cannot take part in the study.

What does the study involve?
Participants will be screened to check if they are able to participate in the study. The screening period will take place for a maximum of 84 days before the start of treatment. Everyone who joins this study will be split into two groups randomly (like flipping a coin) to receive RO7434656, given an injection under the skin on Day 1 at two different doses. Participants will have an equal chance of being placed in either group. Participants will have regular blood tests and will be checked for unwanted effects throughout the study. This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given. During the study, the study doctors will see the participants 7 times during the clinic visits. Participants will be admitted to the clinic 1 day before receiving the treatment (Day -1) and stay in the clinic until Day 4. Participants will have to visit the hospital regularly for up to 90 days. Study doctors will see how well the treatment is working and any unwanted effects participants may have. Total time of participation in the study will be about 6 months. Participants have the right to stop study treatment and leave the study at any time if they wish to do so.

What are the possible benefits and risks of participating?
Participants will not receive any benefits from taking part in the study. However, the information collected in the study can help treat future patients.
It may not be fully known at the time of the study how safe and how well the study treatment works. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options for treatment.
Participants may have unwanted effects of the drug used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of RO7434656 and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Possible unwanted effects include an increased risk of infections, abnormal liver tests, a decrease in the number of blood cells that help blood clot and kidney damage. RO7434656 will be given as an injection under the skin. Potential unwanted side effects include injection-site reactions like redness of the skin (erythema). The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
April 2024 to April 2025

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global.trial_information@roche.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
YA45226

Study information

Scientific Title
A Phase I, open-label, parallel-group study to investigate the pharmacokinetics, pharmacodynamics, safety, and tolerability of a single subcutaneous administration of RO7434656 in healthy adult Chinese participants

Study objectives
The main purpose of this study is to determine the plasma pharmacokinetics (PK) of a single subcutaneous administration of RO7434656 in Chinese healthy adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/06/2024, Peking University First Hospital Ethics Committee (Room 408, Administration Building, No. 74, Xishiku Street, Xicheng district, Peking University First Hospital, Beijing, 100034, China; +86 (0)10-661190259; bdyyec@163.com), ref: Nil known

Study design
Phase I interventional open-label randomized parallel-group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Participants will be randomized to Group 1 or Group 2 in a 1:1 ratio to receive RO7434656. Randomization will be done based on the treatment list generated by independent representatives of the sponsor.

Group 1: Participants will receive a single low dose of RO7434656 as a subcutaneous (SC) injection on Day 1.
Group 2: Participants will receive a single high dose of RO7434656 as a SC injection on Day 1.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
RO7434656

Primary outcome(s)
Plasma concentration and PK parameters of RO7434656 measured using blood samples collected at pre-dose and multiple timepoints post-dose from Day 1 to Day 90 of the Observation Period

Key secondary outcome(s))
1. Change from baseline of plasma Factor B levels following subcutaneous administration of RO7434656 determined using plasma samples collected from Day 1 to Day 90 of the Observation Period
2. Number of participants with adverse events (AEs) and severity of AEs determined according to National Cancer Institute Common Terminology Criteria For Adverse Events (NCI CTCAE), Version 5.0 from Screening to Observation Period (up to approximately 174 days)
3. Number of participants with alanine aminotransferase (ALT) more than 3 * upper limit of normal, assessed using data from electronic case reported forms (eCRF) from Screening to end of Observation Period (up to approximately 174 days)
4. Number of participants with meningococcal and pneumococcal infections, assessed using data from eCRF from Screening to the end of the Observation Period (up to approximately 174 days)
5. Number of participants with injection-site reactions and severity, assessed using data collected in the eCRF from Day 1 to Day 90

Completion date
10/04/2025

Eligibility

Key inclusion criteria
1. Overtly healthy and has no evidence of active or chronic disease as determined by detailed medical and surgical history and the results of a physical examination, vital signs, 12 lead electrocardiogram (ECG), or clinical laboratory tests.
2. Body weight greater than or equal to 50 kilograms (kg) and a body mass index within the range 18.5 to 28.0 kilogram per meter squared (kg/m2)
3. Vaccination against Neisseria meningitidis within 5 years prior to initiation of study treatment
4. Vaccination against Streptococcus pneumoniae within 5 years prior to initiation of study treatment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Treatment with any other investigational drug, biological agent, or device within 4 weeks or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study treatment.
2. Received or is scheduled to receive any live vaccine within 4 weeks prior to the first dose of investigational product or within 90 days after receipt of the investigational product.
3. Received or is scheduled to receive an inactivated vaccine within 1 week prior to the first dose of investigational product or within 90 days after receipt of the investigational product.
4. History or evidence of any medical conditions (e.g., gallbladder removal, malabsorption syndrome, or hepatic disorder) potentially altering the absorption, distribution, metabolism, or elimination of drugs.
5. Social circumstances that increase the risk of infection with bacteria that can cause encapsulated infections
6. History or presence of clinically significant cardiovascular disease, renal disease, hepatic disease, gastrointestinal disease, hematological disease, immunological disease, neurological disease, endocrine disease, metabolic disease, pulmonary disease, or history of any of these diseases with renal, hepatic, or cardiopulmonary dysfunction.
8. Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 3 months after the single SC dose of RO7434656.

Date of first enrolment
10/10/2024

Date of final enrolment
15/10/2024

Locations

Countries of recruitment
China

Study participating centre
Peking University First Hospital
China
100009

Sponsor information

Organisation
F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes